

REMARKS

Claims 10-15 stand rejected under 35 U.S.C. § 103(a)¹ as obvious over Carrano *et al.*, Groswasser *et al.*, Stites *et al.*, and Bouvet *et al.* as stated in the previous Office Action.² For the following reasons, the applicants respectfully traverse.

None of the references, alone or in combination, suggest a method comprising the combination of all the following elements, as recited in the present claims:

- a) parenteral administration to the thigh
- b) of a composition comprising an immunogen of a pathogenic agent having a gateway into the rectal, genital, and/or urinary mucous membranes
- c) in an amount effective to elicit an immune response,

wherein the immune response is a systemic immune response and a local immune response of IgA, IgG, or IgM antibodies or B cells secreting them that is targeted at the rectogenitourinary mucous membranes and lymph nodes that drain it.

In the final Office Action, the Examiner relies primarily on Groswasser and Stites *et al.* for teachings of administering vaccines to the thigh (e.g., quadriceps) for elicitation of an immune response.

However, the claims are not drawn simply to a method of eliciting an immune response by administration to the thigh, and neither Groswasser nor Stites *et al.* teach or suggest that parenteral administration to the thigh of a immunogen having a gateway into the rectal, genital, and/or urinary mucous membranes would result in the recited systemic and local immune response.

The Examiner characterizes the recitation of "inducing a systemic as well as a local immune response of IgA, IgG or IGM or B cells secreting said antibodies that are targeted at the rectogenitourinary mucous membrane and lymph nodes that drain it" as merely an elaboration of the mechanism of the method rather than a manipulative difference in the method steps. The applicants respectively disagree. Claim 10 recites that administration of the immunogen is in an amount

¹ The applicants presume the reference to "102(a)" in the first line of paragraph 2 is a typographical error.

² While the rejection states it is based, in part, on Carrano *et al.*, no arguments based on this reference were proffered. Accordingly, the applicants presume that to the extent Carrano *et al.* is still relied upon it is for the reasons set forth in the previous Office Action, and, therefore, the applicants maintain and reiterate herein by

effective to elicit said immune response, referring back to the type of immune response recited previously in the claim. Accordingly, the phrase referred to by the Examiner is not merely an elaboration of the mechanism of action.

Nevertheless, the Examiner states that Bouvet *et al.* teaches this limitation. The applicants respectfully disagree. Bouvet *et al.* teaches a systemic-derived IgG immune response; Bouvet *et al.* does not teach a local immune response that is targeted at the rectogenitourinary mucous membrane and the lymph nodes which drain it.

Thus, even were one to combine Bouvet *et al.* with either of Groswasser or Stites *et al.*, one would not arrive at the presently claimed invention.

Moreover, as the applicants noted in their previous response, the present invention possesses the unexpected property of being able to induce a local immune response (*i.e.*, in the rectogenitourinary mucous membrane and the lymph nodes which drain it) by injecting an immunogen at a site distant from the rectogenitourinary mucous membranes (*i.e.*, the thigh). (See specification page 2, final paragraph). None of the prior art cited by the Office teaches or suggests such a property. The presence of this unexpected property is evidence of non-obviousness. MPEP 716.02(a). The final Office Action failed to address this issue, and, accordingly, the applicants respectfully request comment on it from the Office.

In summary, while the cited art teaches administration to the thigh as well as induction of a systemic immune response, none of the cited art teaches or suggests both a systemic and local immune response as specified as well as targeting the rectogenitourinary mucous membrane and the lymph nodes which drain it. Moreover, the claimed method possesses the surprising result that a local immune can be induced by injecting an immunogen at a site distant from the rectogenitourinary mucous membranes. In view of the foregoing, the claims cannot be obvious.

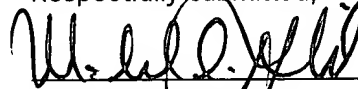
reference their arguments in their previous response as to why the claims are not obvious over Carrano *et al.* alone or in combination with the other cited references.

If there are any questions or comments regarding this Response or application, the Examiner is encouraged to contact the undersigned attorney as indicated below.

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Respectfully submitted,



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